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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,478	05/31/2002	Michael Hayden	SMBG.P-0011	4097
21121	7590	08/19/2004	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,478

Applicant(s)

HAYDEN ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2, 5, 7, 8, 20 and 26, drawn to use of huntingtin protein to regulate cell survival by inhibiting cell death in a neurodegenerative disease, classified in class 514, subclass 12.
- II. Claims 3, 5, 7, 8, 15, 21 and 27, drawn to use of a nucleic acid encoding huntingtin protein to regulate cell survival by inhibiting cell death in a neurodegenerative disease, classified in class 514, subclass 44.
- III. Claims 2, 6, 9-11, 20 and 26, drawn to use of huntingtin protein to regulate cell survival by inhibiting cell proliferation in cancer, classified in class 514, subclass 12.
- IV. Claims 3, 6, 9-11, 15, 21 and 27, drawn to use of a nucleic acid encoding huntingtin protein to regulate cell survival by inhibiting cell proliferation in cancer, classified in class 514, subclass 12.
- V. Claims 12, 17, 23 and 29, drawn to use of an oligonucleotide antagonist of huntingtin protein to regulate cell survival by inhibiting cell proliferation in cancer, classified in class 514, subclass 44.
- VI. Claims 13, 18, 24 and 30, drawn to use of an antibody antagonist of huntingtin protein to regulate cell survival by inhibiting cell proliferation in cancer, classified in class 424, subclass 130.1.
- VII. Claims 14, 19, 25 and 31 drawn to use of a small molecule antagonist of huntingtin protein that binds to huntingtin to regulate cell survival by inhibiting cell proliferation, classified in class 514, subclass 1.
- VIII. Claims 14, 19, 25 and 31, drawn to use of a small molecule antagonist of huntingtin protein that binds to a nucleic acid encoding huntingtin to regulate cell survival by inhibiting cell proliferation, classified in class 514, subclass 1.
- IX. Claims 33 and 34, drawn to an assay for molecules having an anti-proliferative activity comprising transfecting NIH 3T3 cells with huntingtin and culturing the cells with a candidate molecule, classified in class 435, subclass 29.

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- X. Claims 35 and 36, drawn to an assay for molecules having an anti-proliferative activity comprising transfecting NIH 3T3 cells with huntingtin and implanting the cells in an animal in the presence of a candidate molecule, classified in class 424, subclass 9.2.

Claim 1 links inventions I-IV. Claims 1, 4, 6, 9-11, 16, 22 and 28 link inventions V-VIII. Claim 32 links inventions IX and X. The restriction requirement among the inventions is subject to the nonallowance of the respective linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are independent because:

Inventions I-VIII are mutually exclusive and independent methods as each invention is directed to a materially different and separate modulator. Each modulator has a distinct biological function, and a distinct structure. Further, none of inventions I-VIII are required for the implementation of one another.

Inventions I-VIII and either Invention IX or X are mutually exclusive and independent methods. The protocols of the implementation of inventions I-VIII are materially different and separate from the protocols for the methods of invention IX or X. The method of preparing a medicament of inventions I-VIII is not required for either method of assay of inventions IX or X, and vice versa.

Inventions IX and X are materially different and separate methods of assay. Invention IX is to an in vitro assay and invention X is to an in vivo assay. The protocols for the implementation of the methods of assays are materially different and separate. Further, invention IX is not required for invention X, and vice versa.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

August 16, 2004